

## REMARKS

### Claim Status

Claims 1, 4-7, 19, and 27 are amended presently, in order to clarify claim language; claim 18 is canceled without prejudice or disclaimer; and dependent claims 29-31 are new and find support in the as-filed application at, e.g., published paragraph number [0037]. No new matter has been added. Upon entry of this amendment, claims 1-17 and 19-31 will be pending and elected claims 1-7 and 19-31 will be presented for examination.

### Rejections under 35 U.S.C. § 112 (Written Description)

Claims 1-7 and 18-27 remain rejected for alleged lack of “written description” support in the specification. Office action, item 4, at pages 3-6. At the outset, the PTO takes the position “the claims are broadly drawn to a genus of promoter sequences that hybridize under stringent condition to the nucleotide sequence set forth in SEQ ID NO: 2, as well as a genus of promoter sequences that are at least 65% identical to SEQ ID NO: 2.” *Id.* at page 4. In so asserting, however, the PTO alleges “the specification does not describe the structure of any other species in the claimed genus except for SEQ ID NO: 2, itself.” *Id.* Applicants respectfully traverse the grounds for this rejection.

Central to the PTO’s rejection is its allegation that “[n]either the specification nor the prior art teaches the conserved structures that are essential for promoter activity.” *Id.* While acknowledging that promoter sequences, such as the inventive promoter sequences, comprise boxes or other identifiable regions essential for promoter activity, the PTO alleges that the “specification does not describe what are those signaling sequences or boxes in the promoter.” *Id.* at page 5.

The PTO has the initial burden of presenting evidence why a person skilled in the art would not recognize in applicants’ disclosure a description of the invention defined by the claims. *See* MPEP § 2163. While admitting that applicants disclose structural features of the recited sequence (*i.e.*, SEQ ID NO: 2), the PTO provides no evidence explaining why the skilled person would not have understood the metes and bounds of the invention as claimed.

Thus, the PTO bases its rejection on the grounds that applicants allegedly have not described “conserved structures that are essential for promoter activity.” *Id.* Because the PTO has not satisfied its burden, however, the rejection should be withdrawn.

Contrary to the PTO’s stated position, moreover, the present specification necessarily discloses structural features common to members of the claimed genus of polynucleotides. As the PTO admits, the specification discloses SEQ ID NO: 2 itself, which is indisputably central and common to the claimed genus. Thus informed by the structural underpinnings of SEQ ID NO: 2, the skilled person would understand that sequences having 65% identity with SEQ ID NO: 2, wherein said sequences have promoter activity. Here, the disclosed promoters confer cambium/xylem-preferred expression.

Furthermore, one of ordinary skill in the art could determine what regions of a given promoter sequence, such as SEQ ID NO: 2, are necessary for promoter activity. This is so because the bioinformatics community has developed numerous software programs for analyzing nucleic acid sequences, such as promoters. Particularly apropos in this regard are programs such as “Plant CARE (Cis-Acting Regulatory Elements),” publicly available at the time of applicants’ original filing, which allow *in silico* or computer-assisted plant promoter analysis. See <http://bioinformatics.pub.ugent.be/webtools/plantcare/html>, as well as M. Lescot *et al. Nucleic Acids Res.* 30: 325-27 (2002) (Abstract appended). The skilled artisan, using a publicly available program such as Plant CARE, thus would have apprehended readily those regions of a given promoter sequence, such as SEQ ID NO: 2, that could withstand variation and yet direct transcription in a preferred manner, such as cambium/ xylem-preferred expression.

According to the PTO’s own “Guidelines for Written Description,” an examiner must consider identifying characteristics of an inventive nucleotide or amino acid sequence, such as disclosure of partial structure, functional characteristics, known or disclosed correlation between structure and function, and physical and/or chemical properties. Disclosure of any of these characteristics, or combination thereof, sufficiently meet the requirements for written description. Because applicants disclose both structure and function, from this consideration alone, the instant claims surely satisfy the written description requirement of Section 112.

Based on applicant's disclosure and knowledge within the art, the skilled person would conclude that applicants possessed the claimed genus of nucleic acids, based on the disclosure of SEQ ID NO: 2 and readily accessible identifying characteristics. It is beyond reasonable dispute, therefore, that the specification provides written support for claims 1-7 and 18-27, rendering the present rejection improper and subject to withdrawal.

**Rejections under 35 U.S.C. § 112 (Enablement)**

Claims 1-7 and 18-27 remain rejected for alleged lack of enabling support in the specification. Office action, item 7, at pages 6-10. While acknowledging that the specification enables SEQ ID NO: 2 and fragments thereof having cambium/xylem preferred promoter activity in plants and bacteria, the PTO alleges that the specification "does not reasonably provide enablement for any other variants of SEQ ID NO: 2 having cambium/xylem preferred promoter activity or transgenic host cell other than plants and bacteria." *Id.* at page 6. The PTO grounds this rejection on its interpretation of "a nucleotide sequence set forth in SEQ ID NO: 2" *Id.* at page 7 (emphasis in original).

Further, the PTO cites Fourgoux-Nicol *et al.*, *Plant Molecular Biology* 40: 857-72 (1999), as allegedly teaching "isolating DNA fragments using stringent hybridization conditions does not always select for DNA fragments whose contiguous nucleotide sequences is the same or nearly the same as the probe." *Id.* at page 8. Based on the disclosure of Fourgoux-Nicol *et al.*, the PTO alleges "undue experimentation would be required by one skilled in the art to make and use the claimed invention with DNA that has at least 50% sequence identity to the nucleotide sequence of SEQ ID NO: 2." *Id.* at page 9. Applicants respectfully traverse the grounds for this rejection.

As discussed above for "Written Description," the state of the art at the time of filing was advanced such that an ordinarily skilled artisan could identify which nucleotides in SEQ ID NO: 2 could withstand modification/variation and yet still produce a functional promoter sequence having the recited percentage sequence identity with SEQ ID NO: 2. This is so because sequence software programs, such as Plant CARE, are publicly available and intended for this very purpose.

In fact, the PTO's own reference, Fourgoux-Nicol *et al.*, discloses a promoter sequence, and importantly, the authors determined using various sequencing programs known in the art that their promoter sequence contains regions/motifs identified previously in similar plant promoters. Specifically, Fourgoux-Nicol *et al.* discloses a male gametophyte-specific promoter denoted *BnM3.4* that shares structural features with other male gametophyte-specific promoters. See Fourgoux-Nicol *et al.*, Abstract. Thus, the PTO's own reference provides proof positive that the ordinarily skilled artisan could determine which nucleotides in SEQ ID NO: 2 could withstand modification/variation and yet still confer promoter activity.

While applicants do not agree with the PTO's position regarding hybridization conditions, particularly as it relates to promoter binding, the present claims avoid the PTO's concerns. Additionally, and in an effort to advance prosecution, the claims define a host cell as a plant host cell.

Accordingly, the support provided to claims 1-7 and 18-27 by the original specification is enabling, given both applicants' own disclosure of how to practice the claimed invention and the advanced state of the art at the time of filing, are supported by an enabling disclosure.

#### **Rejections under 35 U.S.C. § 102**

Claims 1-7 and 18-27 remain rejected for alleged anticipation by Xue *et al.*, U.S. patent No. 6,420,629. Office action, item 8, at pages 10-11. According to the PTO, "Xue *et al.* teach that 4CL promoter is highly specific for xylem expression in tobacco. Xue *et al.* also disclose expression vector using 4CL promoter and transgenic spruce expressing the vector. Given that without a defined stringent condition, any sequence can hybridize to another sequence, the claims read on any sequence with plant promoter activity." *Id.* at page 10. Applicants respectfully traverse the grounds for this rejection.

In order to anticipate, a reference must disclose each and every element of the claim. MPEP § 2131. Because Xue *et al.* discloses neither SEQ ID NO: 2 nor a nucleotide sequence

having at least 65% sequence identity to SEQ ID NO: 2, this reference could not anticipate the present claims. Accordingly, the rejection is improper and should be withdrawn

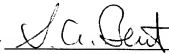
### CONCLUSION

Applicants submit the claims are in condition for allowance, and they respectfully request an early indication to this effect. Also, if there are any questions concerning this application, Examiner Zheng is courteously invited to contact the undersigned counsel directly.

Respectfully submitted,

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By



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The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extension is needed for timely acceptance of submitted papers, applicants petition for such extension under 37 CFR §1.136 and authorize payment of the relevant extension fee(s) from the deposit account.